

PRE-APPEAL BRIEF REQUEST FOR REVIEW

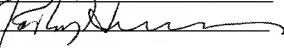
Docket Number (Optional)

388700-058B

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on June 23, 2008 VIA EFS

Signature



Typed or printed name Kathy Hinckley

Application Number

10/763,975

Filed

January 22, 2004

First Named Inventor

Brian J. Cox

Art Unit

3731

Examiner

Confirmation No.

7891

Severson, Ryan J.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.

Registration number 52,263

☐ attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 _____



Signature

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June 23, 2008

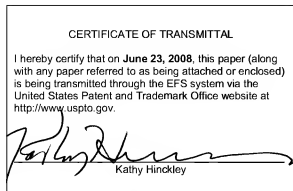
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below.

☒ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PATENT

Applicant: Brian J. Cox
Serial No.: 10/763,975
Filed: January 22, 2004
Title: **ANEURYSM TREATMENT
DEVICE AND METHOD OF USE**
Examiner: Severson, Ryan J.
Group Art Unit: 3731
Confirmation No.: 7891
Atty. Docket No.: 388700-58B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ARGUMENTS RESPONSIVE TO PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

These Arguments are filed responsive to the Applicant's concurrently filed Pre-Appeal Brief Request for Review. In the present application, claims 23-28, 40, and 41 are pending. Claims 29-39, 42 and 43 remain withdrawn and new claims 44 and 45, submitted in the Applicant's Response to Final Rejection, filed May 21, 2008, have not been entered.

As detailed in the Final Office Action mailed February 21, 2008 (the "*Final Office Action*") and the Advisory Action mailed June 10, 2008, pending claims 23-28, 40, and 41 remain finally rejected based on prior art grounds. For the reasons set forth below, the Applicant respectfully submits that these prior art rejections should be withdrawn and the pending claims allowed.

I. THE REJECTION UNDER 35 U.S.C. §103(a) IS IMPROPER

Claims 23-28, 40, and 41 were rejected under 35 U.S.C. §103(a) as being anticipated by U.S. Patent No. 6,231,597 to Deem et al. ("*Deem et al.*") in view of U.S. Patent No. 5,234,456 to Silvestrini ("*Silvestrini*"). Of the pending claims, 23 and 40 are independent. Claims 24-28 depend from claim 23, and claim 41 depends from claim 40. As will become apparent from the following arguments, the rejection is improper (1)

because the Examiner has failed to articulate a rationale underpinning why the Applicants' invention as a whole would have been obvious; and (2) because the Examiner's proposed modification of the prior art improperly changes the principle of operation of the prior art device.

A. THE REJECTION FAILED TO ARTICULATE A RATIONALE UNDERPINNING WHY THE APPLICANT'S INVENTION CONSIDERED AS A WHOLE WOULD HAVE BEEN OBVIOUS

Claim 23 of the present application recites, in part, a bridge portion including a reactive material, said reactive material being expanded when in a reacted state such that said reactive material restricts flow of blood to said vascular aneurysm when said reactive material is in said reacted state. Claim 40 recites, in part, an occlusion region including a reactive material, said reactive material being expanded when in a reacted state such that said occlusion region substantially restricts flow of blood to said vascular aneurysm when said reactive material is in a reacted state. In the *Final Office Action*, the Examiner relies primarily on the teachings of *Deem et al.*, yet acknowledges that *Deem et al.* fail to disclose a reactive material being expandable when in a reacted state. At ¶6, pp. 3-4. To overcome this deficiency, the Examiner asserts that *Silvestrini* teaches a stent that can be expandable material and, apparently for this reason alone, that the Applicant's invention is thereby made obvious. *See id.*

At § 2141 III, the M.P.E.P. quotes the Supreme Court and the Federal Circuit with approval, reciting:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. . . . [R]ejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness

(Internal citation omitted). The present rejection fails to meet this requirement. In the *Final Office Action*, the Examiner simply asserted:

[I]t would have been obvious to one of ordinary skill in the art at the time the invention was made to make the covering (102) of [the] *Deem* reference of the hydrophilic material (26) of [the] *Silvestrini* reference to

allow the reactive material to expand and help occlude the aneurysm neck.

At ¶6, pp. 3-4. This statement merely describes the Examiner's proposed modification and concludes that the modification would be obvious to one skilled in the art. No clear rationale as to why the claimed invention would be obvious was provided.

Similarly, the *Advisory Action* also failed to provide the required articulated rationale. Here, the Examiner stated that the "combination is made to show that both materials are suitable for performing the intended purpose (blocking flow of blood into the aneurysm) and therefore one of ordinary skill in the art would have recognized that more than one type of material may be used to perform the same function." At p. 2, lines 2-5. Contrary to providing a clearly articulated rationale, this assertion is evidence that the Examiner resorted to impermissible hindsight.

For example, it is entirely unclear how combining *Deem et al.* and *Silvestrini* could show that the cover (102) of *Deem et al.* and the expandable filling of *Silvestrini* are suitable for performing the intended purpose of blocking of the flow of blood into an aneurysm. *Deem et al.*, is silent as to employing a cover 102 comprising a material such as that of *Silvestrini*. On the other hand, *Silvestrini's* intended purpose is to maintain an occluded vessel in an open configuration. See BACKGROUND OF INVENTION. The stents of *Silvestrini* are formed, in whole or in part, out of hollow fibers of a permeable membrane within which is disposed a hydrophilic material capable of absorbing liquid. Column 3, lines 35-37. In practice, the stent is placed in the desired location within the vessel and maintained for a period of time sufficient to allow for diffusion of fluid into the membrane and swelling, or expansion, of the hydrophilic material. Column 3, lines 57-65. Upon inflation, the stents independently remain in place by impinging on the interior wall of the lumen. *Id.* Combining the prior art as proposed by the Examiner neither teaches nor makes obvious employing the hydrophilic material as a cover, as opposed to a structural filling, or even blocking of the flow of blood into the aneurysm with an expandable material. Absent a resort to hindsight based on the Applicant's disclosure, there has been simply no logical rationale provided for supporting the present rejection.

Assuming for the sake of argument that a clearly articulated rationale was provided, the rejection fails to consider the invention as a whole. "In determining the difference between the prior art and the claimed invention, the question under U.S.C. 103 is not whether the difference themselves would have been obvious, but whether the claimed invention as a *whole* would have been obvious." M.P.E.P. at § 2141.02 I. As provided above, claims 23 and 40 of the present application recite, in part, a reactive material being expanded when in a reacted state such that said reactive material or said occlusion region substantially restricts flow of blood to said vascular aneurysm when said reactive material is in a reacted state. Considering even just these inventive elements, it is apparent that none of the cited prior art, in combination or independently, teach or make obvious the claims invention. No evidence or rationale has been provided that touches upon a reactive material being expanded such as to restrict flow of blood into an aneurysm.

**B. THE EXAMINER'S PROPOSED MODIFICATION OF THE PRIOR ART IMPROPERLY
CHANGES THE PRINCIPLE OF OPERATION OF THE PRIOR ART DEVICE.**

The Examiner's proposed modification would change the principle of operation of the device of *Deem et al.* Section 2143.01 VI of the M.P.E.P. states, "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." The Examiner based the present rejection on the assertion that it would have been obvious to substitute the cover 102 of *Deem et al.* with the expandable material of *Silvestrini*.

The purpose of the stent of *Deem et al.* is to obstruct flow to an aneurysm while simultaneously minimizing obstruction of flow through the healthy vessel. At column 5, lines 18-22. The principle of operation of the stent of *Deem et al.* is simply the deployment of the stent and the orientation of the predisposed cover 102 so as to block the vascular abnormality. See column 5, lines 45-54. In contrast to cover 102, the hydrophilic material of *Silvestrini* expands in aqueous environments. If one were to make a material substitution, as the Examiner suggests, by making the *Deem et al.* cover 102 out of a hydrophilic material, it is likely that the swelling cover would block the

flow of blood through the vessel. In other words, the Deem et al. cover is already blocking the aneurysm without swelling. There would be no reason to make the cover out of a hydrophilic material because it would likely result in too much material after swelling occurred.

Therefore, in addition to requiring design and construction changes, the proposed modification would also necessarily change, or broaden, the principle of operation of the prior art device to further include expansion of the cover. This change in the principle of operation of the stent of *Deem et al.* is an indication that *Deem et al.* and *Silvestrini* are insufficient to render the present claims *prima facie* obvious.

Turning to claims 24-28 and 41, these claims depend from claim 23 or 40. The rejection of these claims is improper for at least the same reasons as provided above.

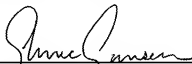
CONCLUSION

In view of the foregoing, it is evident that the present rejection is improper and should be withdrawn. Accordingly, the Applicant submits that pending claims 23-28 and 40 and 41 are in condition for allowance.

If for any reason direct communication with Applicant's attorney would serve to advance prosecution of this case to finality, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any additional fee which may be required in connection with this Amendment to deposit account No. 50-2809.

Respectfully submitted,



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Registration No. 52,263

Dated: June 23, 2008

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